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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/189,702	11/10/1998	ALESSANDRO LETTE	18623-013410	5779

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EXAMINER

SCHWADRON, RONALD B

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 06/03/2003

32

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/189,702

Applicant(s)

ETTE ET AL.

Examiner

Ron Schwadron, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7-9, 11, 12, 14 and 16-24 is/are pending in the application.
- 4a) Of the above claim(s) 12, 14 and 18-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7, 8, 16 and 17 is/are rejected.
- 7) ☒ Claim(s) 9 and 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other:

1. Newly submitted claim 24 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons.

Claim 24 is drawn to a method of treatment as per Group II in paragraph 1 of the Office Action mailed 12/1/2000. The elected invention is a peptide as per Group I in paragraph 1 of the Office Action mailed 12/1/2000. Paragraph 1 of the Office Action also details why these two different inventions were restricted.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 24 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Regarding claim 23 said claim is drawn to a species not currently being examined and therefore said claim is withdrawn from consideration as being directed to a non-elected species. Claim 23 will be rejoined if said peptides are examined as part of claim 7.

2. Claims 7,8,9,11,16,17 are under consideration.

#### RESPONSE TO APPLICANTS ARGUMENTS

3. The abstract of the disclosure is objected to because it does not disclose the currently claimed invention (eg. p53 peptides which bind HLA A2.1). Correction is required. See MPEP § 608.01(b).

Applicants have indicated that they would submit a new abstract pending the outcome of examination .

4. It is noted that applicant has deleted the first paragraph of page 1 of the specification and also indicated that the instant application no longer claims priority to application 08/205713.

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5. In view of the papers filed 12/12/2002, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by the addition of Esteban Celis.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

It is noted that while the petition was erroneously filed under 37 CFR 1.48(b) (used for deleting an inventor), the petition is being treated under 37 CFR 1.48(a).

6. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because the most recent declaration filed listing Esteban Celis as an inventor has a priority claim to application 08/205713, whilst the instant application no longer claims priority to said application. It also contains non-initialed changes to the zip code of inventor Kast.

7. Regarding the IDS filed 7/12/2003, copies of the references were not supplied based on a priority claim to 08/205713. However, priority is no longer claimed to said application.

37 CFR 1.98(d) states that a copy of any patent, publication, pending U.S. application, or other information listed in an information disclosure statement is not required to be provided if: (1) the information was previously cited by or submitted to, the Office in a prior application, provided that the prior application is properly identified in the IDS and is relied on for an earlier filing date under 35 USC 120.

Therefore, the information disclosure statement filed 7/12/2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

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8. It appears that the peptide of SEQ. ID. NO. 4 (SMPPPGTRV) is free of the prior art. The search of the prior art was previously extended to the peptide of SEQ. ID. NO. 15 (CQLAKTCPV). Said peptide has been deleted from the claims filed in the amendment received 2/11/2002 (the amendment mailed by applicant on 1/18/2002). The search is now extended to the peptide of SEQ. ID. NO. 3 (YLSGANLNV). Claim 11 has only been searched with regards to the peptide of SEQ. ID. NO. 4 (eg. the other peptides recited in said claims have not been searched).

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 7,8,16,17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsang et al. in view of Ioannides et al. (US Patent 6,514,942).

Tsang et al. teach the CEA derived peptide CAP-1 (YLSGANLNL, see Table 1). This peptide differs from the claimed peptide at position 9 wherein the claimed peptide contains V instead of L. Ioannides et al. teach a 9mer HLA-A2 binding peptide (see column 32, last paragraph). The claimed peptide also binds HLA-A2. Ioannides et al. teach that a substitution at the ninth residue of their peptide is made wherein V is substituted for M (see column 32, last paragraph). Ioannides et al. also teach that V is the dominant anchor at position 9, wherein L or M are also found at position 9 (see column 32, last paragraph). Tsang et al. teach their peptide in a pharmaceutically acceptable carrier (tissue culture media used in the various assays disclosed in said publication). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Tsang et al. teach the CEA derived peptide YLSGANLNL, which binds HLA-A2, whilst Ioannides et al. teach substitution of V at position 9 wherein V is the dominant anchor at position 9 in peptides which bind HLA-A2 and wherein L or M are also found at position 9. One of ordinary skill would have been motivated to do the aforementioned because Ioannides et al. teach the aforementioned specific substitution and also

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disclose amino acid substituted versions of MHC class I binding tumor peptides (see columns 24 and 25). Ioannides et al. teach CTL peptides linked to proteins that would contain T helper epitopes (see column 26, last paragraph, continued on column 27).

11. Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 11 recites SMPPPGTRV as well as nonelected species which have not been examined. Claim 11 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and if the nonelected species were cancelled.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. No claim is allowed.

14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 305-3014.

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15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.



RONALD B. SCHWADRON  
PRIMARY EXAMINER  
GROUP ~~1600~~ (600)

Ron Schwadron, Ph.D.  
Primary Examiner  
Art Unit 1644